NOT YET SCHEDULED FOR ORAL ARGUMENT
No. 14-5061

IN THE UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

DISTRICT HOSPITAL PARTNERS, L.P., d/b/a The George Washington University Hospital, *et al*.,
Plaintiffs-Appellants,

v.

SYLVIA M. BURWELL, Secretary,
Department of Health and Human Services,
Defendant-Appellee.

On Appeal from the United States District Court
for the District of Columbia
Civil Action No. 1:11-CV-0116-ESH

BRIEF FOR THE APPELLANTS

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CERTIFICATE AS TO PARTIES, RULINGS AND RELATED CASES

Pursuant to Circuit Rule 28(a)(1), Plaintiffs-Appellants, 186 hospitals that participate in the Medicare program (collectively "the Appellants"), by and through their undersigned counsel, hereby certify the following as to Parties, Rulings, and Related Cases:

A. Parties

Pursuant to Circuit Rule 26.1, the undersigned certifies that Appellants, all of which were plaintiffs below, are hospitals that at all times relevant to this action participated in the Medicare program. Attachment A to this brief shows all parent companies and any publicly held company that have a 10 percent or greater ownership interest in Appellants.

Appellee, defendant below, is the Secretary of the United States Department of Health and Human Services, currently Sylvia M. Burwell.

There are no intervenors or *amici curiae* currently in this action in this Court and there also were none in the District Court.

B. Ruling Under Review.

Appellants seek review of the following rulings issued by the United States District Court for the District of Columbia (Ellen S. Huvelle, J.):

Document Name	**Date**	**ECF No.**	**Official Citation**
Memorandum Opinion	07/05/11	14	794 F. Supp. 2d 162

Document Name	Date	ECF No.	Official Citation
Order	07/05/11	15	N/A
Memorandum Opinion and Order	09/10/13	111	N/A
Memorandum Opinion and Order	09/19/13	113	2013 WL 5273929
Memorandum Opinion	01/06/14	124	2014 WL 31430
Order	01/06/14	125	N/A

C. **Related Cases.**

This case was not previously before this Court or any other court. Appellants are unaware of "any other related case," as defined by Circuit Rule 28(a)(1)(C). However, both *Banner Health, et al. v. Sebelius*, Case No. 10-cv-01638-CKK (D.D.C.) and *Buffalo Hospital, et al. v. Sebelius*, Case No. 13-cv-00776-RMC (D.D.C.), include, among other issues, an issue that is similar to the issue presented by this action, with the same defendant but different plaintiffs.

Dated: July 31, 2014

Respectfully submitted,

HOOPER, LUNDY & BOOKMAN, P.C.

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GLOSSARY OF ABBREVIATIONS AND ACRONYMS

APA	--	Administrative Procedure Act
AR	--	Administrative Record
CMS	--	Centers for Medicare & Medicaid Services
CCR	--	Cost-to-Charge Ratio
DRG	--	Diagnosis Related Groups
MedPAR File	--	Medicare Provider Analysis and Review File
IFR	--	Interim Final Rule
OMB	--	Office of Management and Budget
Secretary	--	Secretary of the United States Department of Health & Human Services

I. INTRODUCTION

After thorough vetting by the Centers for Medicare and Medicaid Services ("CMS"), the agency that administers Medicare, the Secretary signed and presented a 64-page Interim Final Rule ("IFR") to the Office of Management and Budget ("OMB"), which was significantly modified before publication in the Federal Register on a non-emergency basis for notice and comment rulemaking. The CMS Administrator testified before Congress that the thorough analysis of the unvarnished facts by the Administrator and CMS actuaries supported the approach that the Secretary signed, but not necessarily the rulemaking as modified and published. Thus, the Secretary was caught between a rock (having made the OMB modifications) and a hard place (the apparent lack of a rational basis for the modified approach).

Knowing that the IFR was never made public (even though a public document), the Secretary, for purposes of making the Medicare payment determinations at issue, pretended it never existed and asserted before the district court that she never considered the approach laid out in detail therein for purposes of setting the payment determinations at issue here. Moreover, she did not mention the alternatives considered in the IFR when responding to a comment that serendipitously (but unknowingly) asked the Secretary about an approach specifically discussed in the IFR. The Secretary would have succeeded at wishing away the IFR but for its fortuitous discovery while this action was pending in the district court.

Once revealed, the Secretary fought to keep the IFR out of the rulemaking records, arguing it was irrelevant because she had never even considered it when preparing the 2004 rulemaking, even though the IFR and 2004 rulemaking at issue were prepared contemporaneously. The district court rejected that argument based on the temporal and substantive overlap between the rulemakings and added the IFR to the 2004 rulemaking record.

This action challenges Medicare underpayments for 2004-2006 that resulted from the Secretary's refusal to (a) consider the approaches in the IFR or (b) explain why rejecting those approaches was reasonable in light of the facts presented and the testimony of the CMS Administrator before Congress. The Secretary's refusal to disclose or consider the alternative approaches in the IFR when making the determinations at issue is procedurally invalid under the Administrative Procedure Act ("APA"), 5 U.S.C. §551 *et seq*., because the Secretary has failed to consider a relevant factor and alternatives to the approaches chosen, and is arbitrary and capricious because the approaches chosen were irrational in light of the available alternative. The Secretary's failure to discuss the IFR, or present a rulemaking record that included what was before the agency when the rulemakings at issue[1] were created,

[1] The rulemakings at issue ("Rulemakings") are: (1) Inpatient Prospective Payment System ("IPPS") FFY 2004 Proposed Rule, 68 Fed. Reg. 27,154 (May 19, 2003), and IPPS FFY 2004 Final Rule, 68 Fed. Reg. 45,346 (Aug. 1, 2003); (2) IPPS FFY 2005 Proposed Rule, 69 Fed. Reg. 28,196 (May 18, 2004), and IPPS FFY 2005 Final Rule,
(footnote continued)

also was arbitrary and capricious. These errors, the Secretary's refusal to otherwise properly address the problems with the Rulemakings, and the resulting underpayments, must be remedied.

II. STATEMENT OF JURISDICTION

Plaintiffs/Appellants invoked the jurisdiction of the district court under 42 U.S.C. §1395oo(f) and 28 U.S.C. §1331, seeking judicial review of the final decision of Defendant/Appellee, Secretary of Health and Human Services ("HHS"), refusing to reimburse Plaintiffs, 186 Medicare-participating hospitals ("the Hospitals") for certain Medicare payments. The district court granted the Secretary's motion for summary judgment in a memorandum opinion and order entered on January 6, 2014. The Hospitals timely filed a notice of appeal on February 28, 2014. This Court has jurisdiction under 28 U.S.C. §1291.

III. ISSUES PRESENTED FOR REVIEW

A. Whether the Secretary failed to consider relevant factors, failed to adhere to the notice and comment requirements of the APA, and otherwise acted arbitrarily and capriciously, by making the Medicare determinations at issue:

> 1. Without properly taking into account and/or explaining the effect of the Secretary's regulatory changes on (a) hospital behavior and (b) calculation of the determinations;

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69 Fed. Reg. 48,915 (Aug. 11, 2004); and (3) IPPS FFY 2006 Proposed Rule, 70 Fed. Reg. 23,306 (May 4, 2005), and IPPS FFY 2006 Final Rule, 70 Fed. Reg. 47,278 (Aug. 12, 2005).

2. Using data that the Secretary previously determined needed to be excluded from the determinations without (a) disclosing that she previously determined such data should be excluded or (b) explaining why she reversed course by including such data;

3. Without disclosing the actual data and methodologies she used to make the determinations; and

4. Without using the best available data.

B. Whether the District Court erred by refusing to compel the Secretary to include in the rulemaking records materials necessary to consider this case properly.

IV. STATUTES AND REGULATIONS INVOLVED

Relevant statutory and regulatory provisions are in the Addendum filed herewith.

V. STATEMENT OF THE CASE

A. Statutory and Regulatory Background

Medicare Outlier Claims

The Secretary administers Medicare, a health insurance program for the aged and disabled through CMS.[2] Since 1983, Medicare pays most general acute care hospitals, including Appellants, for inpatient services using a prospective payment system of predetermined rates based on the diagnosis of the patient at discharge,

[2] Before June 14, 2001, CMS was known as the Health Care Financing Administration. In this brief, we refer to the agency as "CMS," even for events before June 14, 2001.

which will come within one of several hundred diagnosis-related groups ("DRGs"). Each DRG payment is designed to reimburse the cost of the average resource use within a particular DRG relative to the average resources for all DRGs, 42 U.S.C. §1395ww(d)(4), and is predicated on the expectation that over the course of a year payments to a well-run hospital will reasonably exceed their costs for all cases, but the costs of a given case may be greater or less than the Medicare payment.

Medicare patients that are far sicker than average require extraordinarily high resource use that can result in the cost of treatment far exceeding what the hospital can recover from the DRG averaging system. Congress authorizes a hospital to request extra payment for these "outlier" cases:

> (ii) . . . [An IPPS hospital] may request additional payments in any case where charges, adjusted to cost, . . . exceed the sum of the applicable DRG prospective payment rate plus any amounts payable under subparagraphs (B) and (F) *plus a fixed dollar amount determined by the Secretary*.
> (iii) The amount of such additional payment . . . shall be determined by the Secretary and shall . . . approximate the marginal cost of care beyond the cutoff point applicable under clause . . . (ii).

42 U.S.C. §1395ww(d)(5)(A)(ii) and (iii) (emphasis added). As implemented by the Secretary, if a hospital's costs (estimated in accordance with the Secretary's rules) exceed the sum of the DRG payment (and certain other add-ons and factors not at issue here) plus the "fixed dollar amount," the hospital receives 80% of the excess (90% for burn cases) as an "outlier" payment. This "fixed dollar amount" is commonly referred to as the "outlier threshold."

A hospital's actual cost of care cannot be definitively determined until Medicare performs an audit of the hospital's costs for the year in which the care was provided, as reflected in the hospital's Medicare cost report. Because the hospital's *actual* costs of care are not known when a claim is submitted to Medicare for payment, the Secretary *estimates* each hospital's care costs by converting that hospital's charges (which are set by the hospital and known definitively at discharge) to costs by applying the "cost-to-charge ratio" or "CCR" that the Secretary has determined to apply to the hospital during that cost year.[3]

Assume the charges for an inpatient stay were $100,000 for a hospital with a CCR of .40. The Secretary would use $40,000 as the hospital's estimated costs for outlier payment purposes. Reducing these costs by the DRG payment (say $10,000) and the outlier threshold (say $24,000), would leave an outlier base of $6,000, which is multiplied by 80% to yield an outlier payment of $4,800, as follows:

	Example A
Charges	$100,000
x CCR =	.40
Estimated cost	$40,000

[3] *See, e.g.*, 68 Fed. Reg. at 45,476 ("To qualify for outlier payments, a case must have costs above a fixed-loss cost threshold amount (a dollar amount by which the costs of a case must exceed payments in order to qualify for outlier payment). To determine whether the costs of a case exceed the fixed-loss threshold, a hospital's cost-to-charge ratio is applied to the total covered charges for the case to convert the charges to costs. Payments for eligible cases are then made based on a marginal cost factor, which is a percentage of the costs above the threshold.").

DRG Payment	($10,000)
Subtotal	$30,000
-Threshold =	($24,000)
Outlier base	$6,000
x 80% =	.80
Outlier payment	$4,800

Calculating correct outlier payments depends on the use of an accurate CCR. An inaccurately high CCR will insufficiently reduce estimated costs, thereby causing the outlier payment to be too high. In Example B, the hospital's estimated costs from Example A will increase from $40,000 to $60,000 (even if its actual costs have not changed) if the hospital increases its charges from $100,000 to $150,000 in the middle of a year while the Secretary uses the same CCR:

	Example A	Example B
Charges	$100,000	$150,000
x CCR =	.40	.40
Estimated cost	$40,000	$60,000
DRG Payment	($10,000)	($10,000)
Subtotal	$30,000	$50,000
-Threshold =	($24,000)	($24,000)
Outlier base	$6,000	$26,000
x 80% =	.80	.80
Outlier payment	$4,800	$20,800

Calculating CCRs

CCRs are determined by dividing a hospital's audited total Medicare-allowed costs for a fiscal period by its actual total Medicare-allowed charges for the same fiscal period. So, if a hospital in 2010 had $40 million in Medicare-allowed costs and $100 million in Medicare-allowed charges, the CCR would be .40 (40/100). If the

hospital raised its charges in 2011 by 50% to $150 million, while its costs rose by only 5% to $42 million, the CCR would go down to .28 (42/150).

Hospitals file their Medicare cost reports within five months after the close of a fiscal year and the Secretary, acting through one of her contractors, "makes a decision to accept a cost report within 30 days."[4] The Secretary "tentatively settles" the cost report within 60 days, and then issues the "final-settled" audited cost report a year or two later (and sometimes 3 to 5 years later).[5]

Preceding the years here at issue, the Secretary's regulations mandated that CCRs would be determined from audited cost reports, which meant they would typically be several years out of date when applied to charges for a case to determine eligibility for outlier payments. Due to this time lag, a CCR would be inaccurately high, and lead to overstated estimated costs and an improperly high outlier payment, if a hospital raised its charges faster than its costs had grown since the year for which the CCR was calculated. The former regulations also mandated that hospital CCRs be raised to much higher statewide average CCRs if they became too low.

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[4] *Medicare Program; Change in Methodology for Determining Payment for Extraordinarily High-Cost Cases (Cost Outliers) Under the Acute Care Hospital Inpatient and Long-Term Care Prospective Payment Systems*, 68 Fed. Reg. 34,494, 34,497 (Jun. 8, 2003).

[5] "After the cost report is tentatively settled, it can take 12 to 24 months, depending on the type of review or audit, before the cost report is final-settled. Thus, using cost-to-charge ratios from tentative settled cost reports…reduces the time lag for updating cost-to-charge ratios by a year or more." *Id*. at 34,497.

These two features created the basic incentive for "turbo-charging" (*i.e.*, raising charges substantially faster than costs while the CCR used by the Secretary remained unchanged and too high), which allowed certain hospitals to receive outlier payments that far exceeded their costs in the years leading up to the issuance of the Secretary's Outlier Correction Rule in 2003. Initially the subject of the Secretary's emergency rule referenced above, it was replaced with notice and comment rulemaking. 68 Fed. Reg. at 34,494.

The Outlier Correction Rule eliminated turbo-charging by, *inter alia*, subjecting outlier payments made after August 8, 2003 to "reconciliation" if the audit of the hospital's cost and charge data showed that the CCR was inaccurately high and caused the hospital to have been overpaid. *Id*. Such "reconciled" outlier overpayments may be subject to repayment with interest retroactive to the year of payment, thereby providing a strong financial incentive for hospitals to make sure that the Secretary is using the correct CCR. 42 C.F.R. §412.84(i)(1) and (m).

The Annual Medicare Budget for Outlier Payments

Congress required the Secretary to budget at least 5% of total DRG payments for payment of outliers:

> (iv) The total amount of the additional payments made under this subparagraph for discharges in a fiscal year may not be less than 5 percent nor more than 6 percent of the total payments projected or estimated to be made based on DRG prospective payment rates for discharges in that year.

42 U.S.C. §1395ww(d)(5)(A)(iv). The Secretary implements this requirement by setting the outlier threshold so that predicted outlier payments would equal 5.1% of predicted total DRG payments.[6] To pay for outliers, the Secretary is required to make a corresponding 5.1% cut to the national base payment rate (the "standardized amount") for each patient discharge. 42 U.S.C. §1395ww(d)(3)(B). Thus, Congress requires the Secretary to design the annual outlier threshold so that the 5.1% cut in the standard DRG payments is used for outliers.

The Secretary has long taken the positon (upheld by this Court) that retroactive adjustments will not be made to assure that total actual outlier payments for a given year do not exceed 6% or are less than 5% of actual DRG payments.[7] Under this non-cumulative implementation of the outlier statute, each year is budgeted independently.[8] It would therefore be unlawful for the Secretary to "make up" for previous outlier overpayments by purposefully setting a threshold so high as to reduce outlier payments in the budget for the coming year below the 5.1% target.

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[6] *See* 68 Fed. Reg. at 45,478; 69 Fed. Reg. at 49,278; and 70 Fed. Reg. at 47,495.

[7] 62 Fed. Reg. 45,966, 46,011 (Aug. 29, 1997); 70 Fed. Reg. at 47,495; *see also County of Los Angeles v. Shalala*, 192 F.3d 1005 (D.C. Cir. 1999).

[8] This, however, does not deprive individual hospitals of the right to seek correction of individual outlier payments through the appeal process under 42 U.S.C. §1395oo. Nor does it deprive the Secretary of the right to recover outlier overpayments through the reconciliation process under 42 C.F.R. §412.84(i)(4).

Setting the Outlier Threshold

From 1994 through 2002, the Secretary calculated outlier thresholds using a "cost methodology," which inflated actual costs from hospitals' most recent audited cost reports to the upcoming year and then calculated the outlier threshold using various outlier payment simulations. By using actual CCRs, the only predictive variable supplied by the Secretary in the "cost" methodology was the inflation factor, which was based on costs and, therefore, not affected by turbo-charging.

Beginning in 2003 (and in the Rulemakings), the Secretary used a "charge" methodology that included the following two basic steps:

> 1. The Secretary applied an inflation factor to the charges for each and every inpatient DRG case that Medicare processed in the last complete year to project charges for the upcoming year. So, for purposes of calculating the 2004 outlier threshold, the Secretary applied a two-year inflation factor to the charges for inpatient cases for 2002 to project charges for 2004.[9]
>
> 2. The Secretary multiplied the projected comprehensive universe of modeled charges by the CCRs from the "latest tentatively settled cost report" to project the costs for each case for the coming year. *Id.*

[9] "To calculate the FY 2004 outlier thresholds, we simulated payments by applying FY 2004 rates and policies using cases from the FY 2002 MedPAR file. Therefore, in order to determine the appropriate FY 2004 threshold, it was necessary to inflate the charges on the MedPAR claims by 2 years, from FY 2002 to FY 2004." 68 Fed. Reg. at 45,477. The MedPAR file "contains data from claims for services provided to beneficiaries admitted to Medicare certified inpatient hospitals" (*see* http://www.cms.gov/Research-Statistics-Data-and-Systems/Files-for-Order/IdentifiableDataFiles/MedicareProviderAnalysisandReviewFile.html).

Thus, under the "charge methodology," the Secretary uses a predictive inflation factor based on charges (and vulnerable to turbo-charging) to project what charges will likely be in the upcoming year and these projected charges are then reduced to costs using historical CCRs.

Having created this "virtual" universe of inpatient cases for the upcoming year (complete with projected charges and costs), the Secretary plugs various outlier thresholds into software loaded with this virtual universe of claims and DRG payment policies that the Secretary adopted for the upcoming year, until she found a threshold that she stated would hit the 5.1% target. *See, e.g.*, 68 Fed. Reg. at 45,476. The rationality of the Secretary's projection under the "charge methodology" depends entirely on whether the inflation factor and CCRs used were reasonable. Using this process, the Secretary set the threshold at $31,000 for 2004,[10] $25,800 for 2005, and $23,600 for 2006.

For 2004-2006, the "charge methodology" did not work because the Secretary used historical CCRs and projected charges that were too high in light of the change made by the Outlier Correction Final Rule, causing projected hospital costs to be too high. As a necessary consequence, fewer cases qualified for outlier payment under

[10] The 2004 threshold was reduced to $30,150 for discharges occurring April 1, 2004 through September 30, 2004, as the result of changes made by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, §§ 401, 402 and 504, 117 Stat. 2066.

the unjustifiably high threshold, which caused actual outlier payments to be far below the 5% to 6% window set by Congress (the Secretary undershot her 5.1% outlier payment target by $1.4 billion in 2004, $1.1 billion in 2005, and $0.65 billion in 2006). It is now undeniable that the Secretary used inflation factors and CCRs for 2004-2006 that she knew were unreasonably high and would result in thresholds that were unreasonably high, leading inescapably to outlier underpayments.

B. Factual Background

The Recognition and Elimination of Turbo-Charging

If a hospital increases its charges at a faster rate than its costs are rising, the use of historical CCRs will cause its estimated costs for purposes of calculating outlier payments to be higher than its actual costs. The result is outlier payments that would not have been made if the contemporaneous (lower) CCRs had been used.

From 1997 through 2003, outlier payments exceeded the Secretary's 5.1% projection because the Secretary's outlier payment calculation methodology was vulnerable to turbo-charging, which caused high outlier payments to approximately 123 of the approximately 4,000[11] Medicare-participating hospitals. The magnitude of the distortion that a few turbo-charging hospitals could cause can be seen by the outlier payments to one hospital (which did not have a particularly sick patient

[11] *See, e.g.*, 68 Fed. Reg. at 27,408.

population) in 2002, which were more than 215% of its total DRG payments.[12] The $62.5 million paid to that hospital was, by itself, more than 1.1% of the total outlier payments of $5.3 billion made that year and just under 4% of the $1.6 billion that outlier payments exceeded the 5.1% projection for 2002 of $3.7 billion. Scully Testimony at 4 (JAXXX).

Unaware that turbo-charging was causing outlier payments to exceed projections, the Secretary responded by increasing the threshold every year, figuring that doing so would reduce outlier payments to the 5.1% level. This turned out to be ineffective because the small number of hospitals that engaged in turbo-charging caused the increase in their estimated costs used for outlier purposes to outpace the increases to the threshold. The Secretary's approach reached a crescendo in 2003, when she increased the threshold by more than 60%, from $21,025 in 2002 to $33,560 – the highest it has ever been. 68 Fed. Reg. at 34,505.[13]

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[12] *Medicare Outlier Payments to Hospitals: Hearing Before Subcomms. on Appropriations and Labor, Health, and Education*, 108th Cong. 108-268 (2003) at 5 Joint Appendix ("JA") XX ("Scully Testimony"), *available at* http://www.hhs.gov/asl/testify/t030311.html [Dkt 42-2] (identifying a hospital that increased charges from 1999-2001 by 110.7% (*see* chart attached to Scully testimony) and, in 2002, received $29 million in DRG payments and $62.5 million in outlier payments.).

[13] "[N]early all of the increase in the FY 2003 threshold from 2002 ($21,025 to $33,560) was due to a relatively few hospitals with extraordinary rates of increase in their charges." IFR at 15 (JAXXX).

The turning point came in October 2002, when the Secretary read an article by a Wall Street analyst about the effect of "turbo-charging" on Medicare outlier payments. Scully Testimony at 4 (JAXXX). The Secretary immediately took several steps to eliminate that practice, including having Medicare contractors audit hospitals with higher than expected outlier payments. *Id*. at 9 (JAXXX). Also, the Secretary announced in January 2003 that one hospital chain, after "repeated contact from CMS, has voluntarily quit billing for this, and it has cost them $57 million a month, or $750 million a year." *Id*. at 5 (JAXXX).

The Outlier Correction Rule

The Outlier Correction Rule, proposed on March 5, 2003,[14] and finalized on June 9, 2003, ended any possible outlier payment benefit from turbo-charging by subjecting outlier overpayments made after August 8, 2003 (the implementation date of the Outlier Correction Final Rule) to recovery with interest applied retroactive to the time of payment through "reconciliation." 68 Fed Reg. at 34,496 and 34,500-04.

The Final Rule also provided that, instead of using a hospital's most recent audited cost report to estimate costs for outlier payment purposes, Medicare would use (a) an updated CCR provided by the hospital or (b) the CCR from the hospital's "tentative settled" cost report if the tentative settled cost report contained more recent

[14] *Medicare Program; Proposed Change in Methodology for Determining Payment for Extraordinarily High-Cost Cases (Cost Outliers) Under the Acute Care Hospital Inpatient Prospective Payment System*, 68 Fed. Reg. 10,420 (Mar. 5, 2003).

data than the hospital's most recent audited cost report. *Id*. at 34,499. The Secretary also ended her practice of using a statewide average CCR where a hospital's computed CCR fell below a certain floor, in recognition that extremely low CCRs likely were caused by turbo-charging and defaulting to the much higher statewide average CCR actually rewarded turbo-charging hospitals by paying them more for outliers. *Id*. at 34,499-500.

As a result of the changes made by the Outlier Correction Final Rule, the Secretary stated "outlier payments to the hospitals that have been most aggressively increasing their charges to maximize outlier payments will be dramatically reduced." *Id*. at 34,505 (emphasis added). In the Proposed Rule, the Secretary identified "123 hospitals that appear to have been most aggressively gaming the current policy." 68 Fed. Reg. at 10,423-24 and 10,428.[15] The Secretary also identified 43 hospitals that had defaulted to the statewide average because their CCRs were too low. 68 Fed. Reg. 34,499-500.

In the Outlier Correction Proposed Rule, mindful of the reduction in outlier payments that would accompany the elimination of turbo-charging, and that "outlier payments for any year must be projected to be not less than 5 percent" of total

[15] The Secretary noted that, for these 123 hospitals, (a) "the mean rate of increase in charges was 70 percent" while the CCRs for these hospitals "declined by only 2 percent,"and (b) "current outlier payments," on average, "comprise 24 percent of their total DRG payments." *Id*. at 10,424, 428. Surprisingly, the Secretary did not address these 123 hospitals in the Final Rule or any subsequent rule.

estimated DRG payments (68 Fed. Reg. at 10,426), the Secretary discussed a possible immediate reduction in the 2003 threshold (*id*. at 10,427). But the Secretary deferred that decision until the Final Rule, ultimately deciding not to change the threshold. *Id*.

In both the Proposed and Final Outlier Correction Rules, the Secretary noted only three *Alternatives Considered,* each of which she rejected: (1) "not make any changes to the current outlier policy," (2) basing a hospital's CCR on the rate of increase of its charges, and (3) eliminating use of the statewide average for all hospitals. 68 Fed. Reg. at 10,428 (proposed); 68 Fed. Reg. at 34,514 (final). It is clear that the Secretary considered the several other alternatives in the IFR, yet failed to mention them in the Proposed or Final Outlier Correction Rule. Most inexplicably is that the Secretary waited until August 8, 2003 to put in place the policies that would end turbo-charging.

The IFR

While this action was pending in the district court, the Hospitals learned that, in February 2003, before the publication of the Outlier Correction Proposed Rule, both the Secretary and CMS Administrator had signed, cleared, and sent to OMB for review the IFR [Dkt 84-4], which would have immediately (a) changed the outlier policy as of the date of publication (an option not mentioned in the Outlier Correction

Proposed or Final Rules) and (b) reduced the 2003 threshold from $33,560 to $20,760. IFR at 1, 38 (JAXX and XX).[16]

The Secretary stated in the IFR that "[w]e anticipate that most hospitals' cost-to-charge ratios will decline when data from final settled FY 2003 cost reports are used to compute hospitals' final outlier payments under the changes being implemented by this interim final rule with comment period." IFR at 34 (JAXXX). "Applying a lower cost-to-charge ratio," the Secretary stated "results in a lower cost estimate." *Id.* The IFR continues:

> Therefore, if FY 2003 cost-to-charge ratios are used to determine the fixed-loss threshold (rather than cost-to-charge ratios from FY 2000 or FY 1999 cost reports), FY 2003 outlier thresholds would be lower. As a result, it is necessary to recalculate the outlier threshold to be effective for discharges on or after **[insert date of publication]** [sic], so that outlier payments based on FY 2003 cost-to-charge ratios are still projected to be not less than 5 percent nor more than 6 percent of total operating DRG payments plus outlier payments.

IFR at 34 (JAXXX) (bold in original). The IFR thus acknowledges that, for the period from 1999 through 2003, charges were increasing faster than costs for "most" hospitals. *See* 69 Fed. Reg. at 49,277. The Secretary also describes recalculating the threshold in light of the elimination of turbo-charging as a statutory imperative ("it is necessary to recalculate the outlier threshold . . . so that outlier payments . . . are still

[16] Executive Order 12866, 58 Fed. Reg. 51,735 (Oct. 4, 1993) [Dkt 84-5], requires the Secretary to submit all major rulemakings (the Rulemakings are indisputably "major") to OMB for review.

projected to be not less than 5 percent nor more than 6 percent of total operating DRG payments plus outlier payments"). The Outlier Correction Final Rule rejected this approach. 68 Fed. Reg. at 34,505.

The IFR "identified 123 hospitals that had increases in charges in their case-mix adjusted charges[17] of, on average, 70 percent from FY 1999 to 2001. Meanwhile, the cost to charge ratios for these hospitals declined by only 2 percent." IFR at 35 (JAXXX). The distorting effect of turbo-charging hospitals is vividly described, as follows:

> Clearly, the cost-to-charge ratios that will be used to settle these hospitals' FY 2003 cost reports will be much lower than the cost-to-charge ratios computed using data from prior periods. Moreover, these hospitals are receiving disproportionately high outlier payments as a percentage of their total DRG payments (24 percent). In fact, we estimate the existing FY 2003 outlier payments made to these hospitals, which make up about 2 percent of all Medicare-participating hospitals, constitute 21.7% percent of all outlier payments nationally.

IFR at 35 (JAXXX) (emphasis added). Aware of the distorting effect caused by the data from turbo-charging hospitals, the Secretary eliminated their data when calculating whether an immediate change needed to be made to the 2003 threshold.

> We determined that we could not reliably predict the operating or capital cost-to-charge ratios that these 123 hospitals would have in FY 2003; therefore we excluded them from the simulations we used to determine the revised fixed-loss thresholds in this interim final rule with comment period. We believe this is the most appropriate approach

[17] "Case-mix adjusted charges" are intended to correct for differences in illness severity within the same DRG.

> because, historically, outlier payments to those hospitals have been much more in line with the payments made to other hospitals.

IFR at 36 (JAXXX) (emphasis added). The Secretary also identified 43 hospitals that had apparently received higher than necessary outlier payments because of the default to the statewide average. IFR at 21 (JAXXX).

With respect to the charge inflation factor, the Secretary stated:

> In the August 1, 2002 final rule (67 FR 50,124), we described our methodology for inflating charges (from the FY 2001 MedPAR to FY 2003 levels). We used a charge inflation factor of 17.6398 percent. This factor was based on the rate of change in covered charges per case over the 3-year period from FY 1999 to FY 2001. In calculating the fixed-loss threshold for this interim final rule with comment period, we excluded the 123 hospitals mentioned above (because they are excluded from the calculations otherwise) and reestimated the charge inflation factor. The rate of change in charges per case during this period is 15.0250 percent over two years.

IFR at 37-38 (JAXXX). The elimination of the data from the 123 turbo-charging hospitals caused the inflation rate to decline by almost 15%, showing the enormous effect of the very few turbo-charging hospitals. The Outlier Correction Rule, however, was silent on the exclusion of data from the 123 turbo-charging hospitals.

The use of a lower inflation factor, lower CCRs, and CCRs that did not default to the statewide average led to significantly lower projected costs, which resulted in the Secretary determining in the IFR that it was "necessary" to reduce the threshold from $33,560 to $20,760 for the balance of 2003. IFR at 38 (JAXXX). In the "Quantitative Analysis" section of the IFR, the Secretary elaborated that she had

simulated payments for purposes of recalculating the threshold by "excluding the 123 hospitals noted previously for whom we could not reliably predict the [CCRs] that ultimately will be used to pay this hospitals for outliers." IFR at 51 (JAXXX). The elimination of charge inflation data from the turbo-charging hospitals caused the inflation factor to be reduced, which caused projected charges to be lower which, when multiplied against the same CCRs, led to lower projected outlier payments for all hospitals.

The IFR also noted that the elimination of turbo-charging would reduce actual outlier payments to turbo-charging hospitals from the 24% of total DRG payments that they were receiving in 2003 to the 8.9% of total DRGs payments they received in 2000 (the latest year with accurate CCRs). IFR at 52 (JAXXX). This reduced overall outlier payments by 0.8%. IFR at 54 (JAXXX) (Table I, line 1, column 3). By significantly lowering the threshold in the IFR, the Secretary addressed both of these effects, the statutory directive, and the Secretary 5.1% goal by (a) increasing the number of cases for all hospitals that would qualify for outlier payments and (b) reducing the number of cases that would qualify for outlier payments at the 123 turbo-charging hospitals. Thus, the IFR resulted in "the redistribution of approximately $420 million in outlier payments" from the 123 turbo-charging hospitals to the approximately 3,800 non-turbo-charging hospitals. IFR at 52-53(JAXXX-XX).

The Scully Testimony

On March 11, 2003, the CMS Administrator told Congress that the Secretary had comprehensively addressed "turbo-charging" in the Outlier Correction Proposed Rule, published on March 5, 2003, which "would prevent further gaming of the system by a few hospitals." Scully Testimony at 4-5 (JAXXX). As a result of the publication of the Outlier Correction Proposed Rule, "I have argued strongly within the administration that we should lower the threshold [from $33,560 for FFY 2003] back to $22,000 or $23,000" (*id.* at 12 (JAXXX)) and "I happen to believe, and our actuaries believe that the correct number probably is in the midtwenties, if we fix the program abuses." *Id*. at 13 (JAXXX).

This reduction was not made because Mr. Scully said that OMB would not agree to it. Scully Testimony at 13 (JAXXX) ("[F]rom OMB's view, their view is, we [*i.e*. CMS] have been wrong [about the threshold] 5 years in a row, how could we be right"). Thus, the Outlier Correction Rule was issued in proposed form (not as an interim final rule), leaving the 2003 outlier threshold untouched at $33,560 (rather than reducing it to $20,760).

The 2004 Rulemaking

The 2004 outlier threshold was the first calculated after the Secretary published the Outlier Correction Final Rule on June 9, 2003. The 2004 Proposed Rule noted that the three changes proposed to be made by the Outlier Correction Proposed Rule

(using more up to date CCRs, no automatic default to the statewide average for low CCRs, and reconciliation) had not been factored into the proposed outlier threshold calculation because the Outlier Correction Rule had not been finalized, but that the changes in the Outlier Correction Final Rule "will be reflected in the analysis used to establish the final FY 2004 threshold." 68 Fed. Reg. at 27,235. The 2004 Proposed Rule included a projected outlier threshold of $50,645. *Id*.

The 2004 Final Rule used language similar to 2004 Proposed Rule to describe the three changes made by the Outlier Correction Final Rule, which was reflected in the 2004 Final Rule and caused the final outlier threshold to be reduced from $50,645 to $31,000. 68 Fed. Reg. at 45,476-77. This threshold was changed to $30,150 for discharges occurring April 1, 2004 through September 30, 2004. Pub. L. No. 108-173, §§ 401, 402 and 504, 117 Stat. 2066.

Inflation Factor. Despite the adoption of the Outlier Correction Final Rule on June 9, 2003, the 2004 Final Rule continued "to use the 2-year average annual rate of change in charges per case to establish the FY 2004 threshold. The 2-year average annual rate of change in charges per case from FY 2000 to FY 2001, and from FY 2001 to FY 2002, was . . . 26.8 percent over 2 years." 68 Fed. Reg. at 45,476. The 26.8% charge inflation factor that the Secretary used to project the 2004 outlier threshold was knowingly derived from data that reflected the historical turbo-charging that was halted by the Outlier Correction Final Rule.

In the IFR, the Secretary explained that eliminating the data from these 123 hospitals (which reduced the inflation factor by almost 15%) was "the most appropriate approach." IFR at 37-38 (JAXXX). The 2004 Final Rule did not explain why (a) it was appropriate to use data from the time of significant turbo-charging to project charge increases for a time when the Secretary had eliminated turbo-charging and (b) why elimination of the data from the 123 hospitals was no longer the "most appropriate approach."

CCRs. In the 2004 Proposed Rule, the Secretary used CCRs from the most recently audited cost reports in accordance with her unchanged outlier policy. 68 Fed. Reg. at 27,235. In the 2004 Final Rule, the Secretary purported to use "more recent" CCRs from "the latest tentatively settled cost report," stating:

> After the changes in policy enacted by the final outlier rule this year, it is necessary to calculate more recent cost-to-charge ratios because fiscal intermediaries will now use the latest tentatively settled cost report instead of the latest settled cost report to determine a hospital's cost-to-charge ratio. Therefore, to approximate using the latest tentative settled cost reports in our estimate of the FY 2004 outlier threshold, we calculated updated cost-to-charge ratios using the following three steps: for each hospital, we matched charges-per-case to costs-per-case from the most recent cost reporting year; we then divided each hospital's costs by its charges to calculate the cost-to-charge ratio for each hospital; and we multiplied charges from each case in the FY 2002 MedPAR (inflated to FY 2004) by this cost-to-charge ratio to calculate the cost per case.

68 Fed. Reg. at 45,476. However, the Secretary noted that "for most hospitals, the latest available cost data are from FY 2000." *Id*.

Because, as the Secretary noted in the IFR, "[w]e anticipate that most hospitals' cost-to-charge ratios will decline when data from final settled FY 2003 cost reports are used to compute hospitals' final outlier payments under the changes being implemented by this interim final rule with comment period" (IFR at 34 (JAXXX)), using CCRs based on 2000 data obviously resulted in higher CCRs, and higher projected outlier costs, than would have occurred if more recent lower CCRs had been used.

Excluding CCRs from Turbo-Charging Hospitals. The 2004 Proposed Rule did not include any adjustments to eliminate the effect of distorting data from turbo-charging hospitals, despite the IFR stating that this was the "most appropriate approach." The 2004 Final Rule does not (a) mention the 123 turbo-charging hospitals, (b) explain why it is proper to include their projected outlier costs and CCRs, or (c) explain why excluding their data is no longer the "most appropriate" approach.

The 2004 Final Rule references "approximately 50 hospitals we believe will be reconciled" because they were "consistently overpaid." 68 Fed. Reg. at 45,476. For these hospitals, the Secretary "attempted to project each hospital's cost-to-charge ratio based on its rate of increase in charges per case based on FY 2002 charges, compared to costs (inflated to FY 2002 using actual market basket increases)." *Id*. at 45,477. Thus, the Secretary did not use for these hospitals (a) actual CCRs for 2003 or (b)

actual cost data for 2002. Apparently, the Secretary was not successful at even this approach, as she stated only what she had "attempted" to do, and did not disclose the CCRs that were used for these hospitals. The Secretary entirely abandoned adjustments relating to reconciled hospitals in the 2005 and 2006 Rules, but noted in the "Quantitative Impact Analysis" section of the 2004 Final Rule that the changes made by the Outlier Correction Final Rule, including to turbo-charging hospitals that are "subject to reconciliation," "have no impact on overall spending" even though "the changes among specific categories of hospitals are quite dramatic." 68 Fed. Reg. at 45,662-63. Hospitals "expected to have a dramatic reduction in their [CCRs]," will be "negatively impacted," while hospitals "not expect to experience dramatic changes in their [CCRs] benefit from the decline in the threshold." *Id*. at 45,662.

Comment Regarding Turbo-Charging Hospital Data. A 2004 Rulemaking commenter specifically requested that the Secretary address turbo-charging hospitals:

> One commenter requested that CMS factor in the calculation of the threshold the fact that certain hospitals have distorted their charges significantly.

Id. The Secretary did not respond to any of these comments in any meaningful way, noting only that the changes made in the Outlier Correction Final Rule "have resulted in a substantial reduction in the outlier threshold from the proposed rule." *Id*.

For 2004, CMS estimated outlier payments at 3.5% of total DRG payments (70 Fed. Reg. at 47,496), significantly lower than the 5.1% target, which amounts to a 2004 outlier underpayment of approximately $1.4 billion.

The 2005 Rulemaking

The 2005 Proposed Rule largely followed the 2004 Final Rule and included a proposal to raise the threshold from $30,150 to $35,085. 69 Fed. Reg. at 28,375. This was astonishing because the Secretary noted in the 2005 Proposed Rule that "[w]e currently estimate that actual outlier payments for FY 2004 will be approximately 4.4 percent of actual total DRG payments, 0.7 percentage points lower than the 5.1 percent we projected in setting outlier policies for FY 2004." *Id*. at 28,377. Despite this impending shortfall, the Secretary left the 2004 threshold untouched.

In the 2005 Final Rule, the Secretary (as described below) changed the methodology for calculating the inflation factor, which reduced the outlier threshold to $25,800. 69 Fed. Reg. at 49,278 The Secretary said that changes were necessary because of the changes that the Outlier Correction Final Rule made to the methodology and "the exceptionally high charge inflation that is reflected in the data for FYs 2001, 2002, and 2003." *Id*. at 49,277.

Inflation Factor. In the 2005 Proposed Rule, the Secretary used a 2-year average annual rate of change in charges per case to inflate 2003 charges to approximate 2005 charges. The Secretary recognized that her "proposed outlier

threshold for FY 2005 was higher than might have been anticipated on the basis of the more up-to-date and, generally, lower cost-to-charge ratios used in [her calculations]." 69 Fed. Reg. at 49,276. She attributed her inaccurate projection to the use of the 2-year average annual rates of change employed to calculate the inflation adjustment factor, which she had used in 2004.

In the 2005 Final Rule, the Secretary changed course:

> Instead of using the 2-year average annual rate of change in charges per case … we are taking the unprecedented step of using the first half-year of data from FY 2003 and comparing this data to the first half year of data for FY 2004. We believe this comparison will result in a more accurate determination of the rate of change in charges per case between FY 2003 and FY 2005.

69 Fed. Reg. at 49,277. This reduced the inflation factor from 26.8% in the Proposed Rule (69 Fed. Reg. 28,376) to 18.76% in the Final Rule (69 Fed. Reg. 49,277), and the threshold went from $35,085 to $25,800.

CCRs. In the 2005 Rulemaking, the Secretary did nothing to adjust the CCRs, which were still derived from the turbo-charging era, when projecting hospital payments.[18]

Even with the significant reduction in the threshold, for 2005, CMS estimated outlier payments at 4.1% of total DRG payments (70 Fed. Reg. at 47,496),

[18] *Id.* at 49,277-78 ("We do not believe that it is necessary to make a specific adjustment to our methodology for computing the outlier threshold to account for any decline in cost-to-charge ratios….").

significantly lower than the 5.1% target, which amounts to a 2005 outlier underpayment of approximately $1.1 billion.

The 2006 Rulemaking

The 2006 Proposed Rule largely followed the 2005 Final Rule to project an outlier threshold of $26,675. 70 Fed. Reg. at 23,469. The 2006 Final Rule did not include any significant policy changes while reducing the projected outlier threshold of $23,600. 70 Fed. Reg. at 47,494.

Inflation Factor. For 2006, the Secretary retained the same methodology that was used to calculate the inflation factor for 2005, resulting in an inflation factor of 14.94%. 70 Fed. Reg. at 47,494.

CCRs. In the 2006 Rulemaking, the Secretary again did nothing to adjust the CCRs, which were still derived from the turbo-charging era, when projecting hospital payments.

Explanation for Outlier Underpayments for 2004 and 2005. In the 2006 Final Rule, the Secretary stated that 2004 and 2005 outlier payments failed to meet the 5.1% statutory minimum because of "special circumstances" that "made it especially difficult to project the increase in Medicare charges when calculating the outlier threshold." *Id*. For 2004, the Secretary stated that "the projected rate of charge inflation used to set the outlier threshold in the IPPS rule for FY 2004 [which was based on the charge inflation rate for 2000-2002] was substantially in excess of the

actual rate of charge inflation during FY 2004," because "[w]e believe that hospitals changed their charging practices" as a result of the Outlier Correction Final Rule. *Id*.

The Secretary stated that projecting charge inflation for 2005 also was difficult because "all" the data that the Secretary used to do so "reflected charges from discharges that occurred before the effective date" of the Outlier Correction Final Rule. *Id*. at 47,494-95. The Secretary concluded that "the charge inflation used for setting both the FY 2004 and FY 2005 cost thresholds was atypical because of the significant growth in hospital charges in the years preceding the change to outlier policy as well as the instability in hospital charging practices that followed the adoption of our new outlier policy." *Id*. at 47,495.

The Secretary, however, did not explain why she did not (as in the IFR) exclude the data from turbo-charging hospitals when calculating the 2004 and 2005 thresholds. She also did not explain why she did not make any changes to take into account that CCRs were declining during the period of high charge inflation.

For 2006, CMS estimated outlier payments at 4.5% of total DRG payments (72 Fed. Reg. 24,680, 24838 (May 3, 2007)), significantly lower than the 5.1% target, which amounts to a 2006 outlier underpayment of approximately $0.65 billion.

The 2004-2006 Rulemaking Records

The district court ordered the Secretary to provide witnesses for three depositions and answer seven interrogatories because of concerns that the rulemaking

records submitted by the Secretary for 2004-2206 were not complete (discovery was ordered after the Secretary conceded that the 2004 rulemaking record was incomplete because she could not find all of the comments that had been submitted). After completion of the discovery, the Hospitals moved the district court to compel the Secretary to add the following to the rulemaking records**:**

> 1. The undisclosed complete and "trimmed" versions of all MedPAR files (such as the 2000 and 2001 MedPAR files), Impact files, and other data files before Secretary when she established the 2004-2006 outlier thresholds;
>
> 2. All public comments received by the Secretary addressing the outlier thresholds for 2004-2006, including the Federation of American Hospitals' comment seeking a threshold to $25,375 for 2004;
>
> 3. The data used by the Secretary to "approximate" the CCRs from tentatively-settled hospital cost reports for the purpose of setting the 2004 threshold;
>
> 4. All data used by one of the Secretary's contractor to develop the outlier thresholds for 2004-2006;
>
> 5. The IFR; and
>
> 6. The Scully Testimony.

The district court's September 19, 2013 Memorandum Opinion and Order [Dkt 113] added to the rulemaking record for 2004 the IFR and Federation of American Hospitals' comment seeking a threshold to $25,375 for that 2004, but otherwise denied the Hospitals' motion.

The District Court's Decision

The Hospitals requested and were granted expedited judicial review of the Secretary's final determinations of the 2004-2006 outlier thresholds. The district court affirmed the Secretary's determinations, granting the Secretary's motion for summary judgment.

The court held that the Secretary generally had no duty to address the options presented in the IFR as part of the 2004 rulemaking because the IFR "never represented agency policy." January 6, 2014 Memorandum Opinion at 11 (JAXXX). Because the court excluded the IFR from the rulemaking records for 2005 and 2006, it held that the Hospitals were "barred" from making arguments about the IFR with respect to those rulemakings. The court also held that the Secretary was "under no duty" to explain why she excluded the data from the 123 turbo-charging hospitals from the inflation calculation in the IFR, but included that data in the calculation for 2004, because the exclusion of this data "is not the type of 'reasonably obvious alternative" for which an agency must explain its rejection," particularly when "unprompted by commenters." *Id*. at 11-12 (JAXXX).

The district court addressed the Hospitals' argument that the Secretary failed to adequately explain how she approximated CCRs for 2004 by acknowledging that the Secretary's description of the approximation process "may not be a paragon of clarity," but "it is not so unclear as to be unreasonable. *Id*. at 17 (JAXXX). The court

rejected the Hospitals' argument that the Secretary, aware of declining CCRs from 2001 through 2003, acted unreasonably by using CCRs from no later than 2002 (and mostly from 2000), finding that the Hospitals "offer no specific suggestions as to how the Secretary should have accounted for a trend in decreasing [CCRs]," ignoring that the Secretary herself had addressed this issue in the IFR by excluding CCRs from the 123 hospitals she found had engaged in turbo-charging. *Id*. at 18 (JAXXX). The court rejected the Hospitals' challenges to the 2005 and 2006 Rulemakings on similar grounds.

VI. SUMMARY OF THE ARGUMENT

In 1994, the Secretary changed from using a "charge methodology" to a "cost methodology" to calculate the outlier threshold because charges were increasing faster than costs, causing declining CCRs and overstated costs, leading to outlier thresholds that were too high. Unaware that the increase in outlier payments was due, primarily, to turbo-charging, in 2002 the Secretary returned to a "charge methodology."

Several months after the return to the "charge methodology" in 2002 the Secretary learned that outlier payment increases were being caused by a small group of hospitals that had been engaging in turbo-charging. The Secretary promptly took a series of regulatory actions that culminated in the publication of the Outlier Correction Rule that eliminated turbo-charging.

Based on her experience with the "charge methodology" a decade earlier, the Secretary knew that turbo-charging hospitals caused charge and CCR data to be so high as to distort outlier payments to all hospitals. The Secretary, therefore, signed and sent to OMB the IFR, to eliminate turbo-charging *immediately*. In doing so, the Secretary acknowledged that this immediate policy change would require certain adjustments to prevent outlier payments from falling fall below the Secretary's 5.1% target and the range intended by Congress. These adjustments would (a) eliminate the distorting turbo-chargers' charge data and CCRs from the outlier threshold calculation and (b) take into account the significant reductions in the outlier payments to the turbo-chargers (from 24% to 8.9% of total outlier payments) and (c) allow the outlier threshold to drop such that a larger number of cases would qualify for outlier payments at more hospitals providing, as the Secretary noted in the IFR, for $420 million to be redistributed to other deserving hospitals. IFR at 52-53 (JAXXX-XX).

Had the Secretary made these same IFR changes in the 2004-2006 Rulemakings, the issue here would likely never have arisen. However, despite the IFR and the Secretary's own experience with the "charge methodology," the 2004-2006 Rulemakings (a) included the distorting charge data from the turbo-chargers, (b) relied on obsolete and too high CCRs from the turbo-chargers, and (c) made no adjustment for the significant reduction in overall outlier payments resulting from the reduction of the portion of payments going to turbo-chargers. As a result, the

Secretary undershot her outlier payment target by $1.4 billion in 2004, $1.1 billion in 2005, and $0.65 billion in 2006.[19]

Knowing that the IFR was never made public (even though disclosable), the Secretary pretended it never existed in later relevant rulemakings. For the Rulemakings here, the Secretary pretended she never considered the approaches laid out in detail in the IFR. The Secretary also never discussed (a) the approaches in the IFR as alternatives considered or (b) her decision in the IFR to exclude turbo-chargers' charge data, not even when responding to a comment serendipitously (but unknowingly) asking the Secretary about doing just that. The Secretary would have succeeded at wishing away the truth if not for the fortuitous uncovering of the IFR while this action was pending in the district court.

Once revealed, the Secretary sought to keep the IFR out of the rulemaking record by arguing it was irrelevant because she had never even considered it when preparing the 2004 Rulemaking, even though both rulemakings were prepared contemporaneously. The district court rejected this argument based on the temporal and substantive overlap between the rulemakings and added the IFR to the 2004 Rulemaking record.

[19] The Secretary acknowledged these shortfalls at 70 Fed. Reg. at 47,496 for 2004 and 2005 and 72 Fed. Reg. at 24,838 for 2006.

This action challenges Medicare underpayments for FFYs 2004-2006 that resulted from the Secretary's refusal to (a) follow the IFR or (b) explain why she did not in light of the facts presented and the testimony of the CMS Administrator before Congress. The Secretary's refusal to follow the IFR was arbitrary and capricious because the alternative approaches chosen were irrational in light of the facts presented. The Secretary's failure to discuss the IFR , or present a rulemaking record that included what was before the Agency when the Rulemakings were created, also was arbitrary and capricious. These errors, the Secretary's refusal to otherwise properly address the problems with the Rulemakings, and the resulting outlier underpayments, must be remedied.

VII. STANDARD OF REVIEW

This Court reviews *de novo* the rulings on appeal, including the district court's grant of summary judgment. *Pub. Citizen, Inc. v. HHS.*, 332 F.3d 654, 658 (D.C. Cir. 2003). This Court's review is governed by 5 U.S.C. §706(2)(A), which requires the Court set aside agency actions that are "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law."

VIII. ARGUMENT

A. The Secretary's 2004-2006 Outlier Thresholds Are Arbitrary and Capricious and Must be Set Aside.

1. The Secretary determines the outlier threshold under the "charge methodology" by creating a virtual universe of inpatient cases for the upcoming year.

The accuracy of the Secretary's outlier threshold depends on whether the inflation factor used to project charges is reasonable in light of the CCRs used to reduce projected charges to projected costs. An improperly high inflation factor or improperly high historical CCRs, or both, will result in projected costs that are too high. If projected costs are over-estimated, the outlier threshold necessary to hit the 5.1% target will be set too high and both the number of qualifying cases and the payments for them will be understated. Knowingly using CCRs and other data that will result in an outlier threshold that will never resemble reality is arbitrary and capricious.

As a simplified example, assume total DRG costs for the base year were $100 billion and that the combination of the Secretary's improperly high inflation factor and historical CCRs caused the projected total DRG costs for the upcoming year to be $120 billion, when use of a proper inflation factor and correct CCRs would have reduced these projected costs to $110 billion. To meet the 5.1% target, the Secretary will set the outlier threshold so that total projected outlier payments will be $6.171 billion (5.1% of $120 billion), where the threshold should be set so that total projected outlier payments will be $5.61 billion (5.1% of $110 billion). If actual total DRG payments end up at $110 billion, outliers will be underpaid by $561 million because of the improperly high threshold.

2. For more than 97% of hospitals, the charge inflation factor was not a significant concern during the years at issue because these hospitals raised their charges only slightly faster than their costs increased. IFR at 17-18(JAXXX-XX). Thus, the use of projected charges and historical CCRs for these hospitals would cause relatively small, but still material, distortions to the outlier threshold calculation.

By contrast, data from the 123 hospitals that had engaged in turbo-charging before 2004 significantly distorted the charge inflation factor that the Secretary used to set the 2004-2006 thresholds. Because they had raised their charges significantly faster than their costs were increasing (68 Fed. Reg. at 10,423) the true CCRs for these hospitals were rapidly declining and the Secretary's use of historical CCRs distorted the projected costs for these hospitals' claims. Also, including the charge inflation data from turbo charging hospitals caused the average charge inflation factor for all hospitals to be too high. The inclusion of projected charges from turbo-charging hospitals caused the inflation factors used in the 2004-2006 Rulemakings to be significantly overstated and not mitigated by representative (contemporaneous) CCRs.

3. The Outlier Correction Rule ended turbo-charging. Therefore, when calculating the 2004-2006 thresholds, the Secretary had to decide what to with the charge data from turbo-charging hospitals. The Secretary knew that using such data skews upward the charge inflation factor, which would result in projected charges that would not be properly reduced to costs because of the Secretary's continued use of

historical (too high) CCRs. The Secretary also had to take into account that the Outlier Correction Rule would cause outlier payment to turbo-charging hospitals in the coming year to be significantly reduced because of the use of current CCRs.

The IFR, the Scully Testimony, and the Secretary's Rulemakings identified 123 turbo-charging hospitals whose "dramatic increases in charges . . . are not reflected in their [CCRs]." IFR at 18 (JAXXX). In the IFR, the Secretary addressed the distortion caused by these hospitals by excluding their data entirely from the outlier threshold calculation, explaining that "this is the most appropriate approach." IFR at 36 (JAXXX). The exclusion of these hospitals' data caused the two-year inflation factor for 2003 to decrease from 17.6398% to 15.0250%. IFR at 38 (JAXXX). The exclusion of this data also caused projected outlier payments to drop considerably, prompting the Secretary in the IFR to reduce the threshold for the remainder of 2003 from $33,560 to $20,760 so that "outlier payments based on FY 2003 cost-to-charge ratios are still projected to be not less than 5 percent nor more than 6 percent of total operating DRG payments plus outlier payments." IFR at 34 (JAXXX).

4. In the 2004-2006 Rulemakings, the Secretary never discussed the option of excluding the data from turbo-charging hospitals. Rather, the steps taken to reduce the thresholds for 2004-2006 were limited to (a) using slightly updated (but still historical) CCRs, (b) eliminating the default to statewide average CCRs for turbo-charging hospitals and (c) for 2004, "attempting" to project CCRs for 50 hospitals the

Secretary said she "believe[d] would be reconciled." This resulted in underpayments that the Secretary knew would occur because of the combination of the high inflation factors and the too high CCRs.

Although the Secretary did not address steps she should take to mitigate charge inflation at all in the 2004 Rulemaking, she did so, as discussed below, for 2005 and 2006 by incorrectly suggesting that the increase in hospital charges in the years at issue was due to general charge inflation by all hospitals, rather than the "dramatic increase in charges" by the 123 turbo-chargers. IFR at 18 (JAXXX). While the steps that the Secretary took in 2005 and 2006 materially reduced the inflation factor (from 26.8% in 2004, to 18.76%, in 2005, to 14.94% in 2006), and helped reduce the outlier underpayment (from $1.4 billion in 2004, to $1.1 billion in 2005, to $0.65 billion in 2006), the more reasonable inflation factor could not fully overcome the distortion the Secretary perpetuated by continuing to use of turbo-charging hospital data and CCRs now knowingly obsolete and too high, thus resulting in continuing underpayments.

In *County of LA*, this Court reviewed outlier threshold determinations under circumstances similar to those presented here. In both cases, the Secretary was faced with choices about what data she should use to set the threshold after a paradigm shift in payment methods that were intended to influence hospital behavior. In *County of LA*, the 1983 paradigm shift was from "reasonable cost" reimbursement to the DRG payment system. 192 F.3d at 1010. The 2003 paradigm shift was from an outlier

payment methodology vulnerable to turbo-charging to a revamped payment model that eliminated turbo-charging.

In *County of LA*, the Secretary chose to rely on data from the earlier "reasonable cost" payment paradigm period (1981), even though the Secretary had used, for other purposes, more recent data (from 1984), which reflected the effect of the change to the DRG system. *Id*. at 1021-22. This Court rejected the Secretary's explanation for using the outdated data as "counter to the evidence before the agency." *Id*. at 1010, 1021-22. This Court remanded that case to the Secretary "either to recalculate the outlier thresholds for fiscal years 1985 – 1986 or to offer a reasonable explanation for refusing to use the 1984 data in setting outlier thresholds during those years." *Id*. at 1023.[20]

Here, despite the Outlier Correction Final Rule, the Secretary set the thresholds for 2004-2006 using predictive data from the bygone turbo-charging years which, based on the IFR, obviously did not reflect the Secretary's expectations about the impact of the elimination of turbo-charging. Not only was the Secretary's explanation of the choices she made when calculating the 2004-2006 thresholds insufficient, she did not explain at all the options presented in the IFR and why they were rejected. The IFR shows that the Secretary knew precisely how to neutralize the distorting

[20] In *Alvarado Comm. Hosp. v. Shalala*, 155 F.3d 1115 (9th Cir. 1998), the Ninth Circuit similarly found that the Secretary's actions were arbitrary and capricious and ordered the thresholds to be reset using 1984 data.

effects of the data from turbo-charging hospitals so that the "charge methodology" would work under the new payment paradigm.

> 1. *The Secretary Acted Arbitrarily and Capriciously when Setting the 2004-2006 Outlier Thresholds by Refusing to Exclude Inflation Data from Turbo-Charging Hospitals, or Otherwise Addressing the Distortion Caused by Charge Inflation.*

1. In the 2004 Rulemaking, which was prepared while the Secretary was also preparing the Proposed and Final Outlier Correction Rule and the IFR, the Secretary did not mention the option of excluding the data from turbo-charging hospitals, despite the following 2004 Rulemaking comment:

> One commenter requested that CMS factor in the calculation of the threshold the fact that certain hospitals have distorted their charges significantly.

68 Fed. Reg. at 45,477. The Secretary "non-response" was that the final threshold had been reduced significantly from what the Secretary had proposed, which is particularly disingenuous given that the proposed threshold was set in excess of $50,000 approximately two months after the CMS Administrator testified to Congress that the threshold should be half that amount. This "alone require[s] that [the Court] reverse as arbitrary and capricious," *Fox Television Stations, Inc. v. FCC*, 280 F.3d 1027, 1051 (D.C. Cir. 2002), for "[t]he opportunity to comment is meaningless unless the Agency responds to significant points raised by the public,'" *Home Box Office, Inc. v. FCC*, 567 F.2d 9, 35-36 (D.C. Cir. 1977).

Moreover, the Secretary did nothing to the inflation factor in the 2004-2006 Rulemakings to account for the distorting effect of data from turbo-charging hospitals, nor did she explain why including the data was reasonable. The 2004 Final Rule used an unmitigated two-year inflation rate of 26.8%. Although the 2004 Rulemaking mentioned the Secretary's "attempt" to project CCRs for "approximately 50 hospitals we believe will be reconciled," the Secretary has never divulged (despite the Hospitals' motion to compel) the data from this "attempt" that was used in the 2004 Rulemaking. Moreover, nothing in any of the Rulemakings suggests that the Secretary did anything to mitigate the distorting effect of the data from these 50 hospitals (or turbo-charging hospitals).

2. In 2005, the Secretary changed her methodology for calculating the inflation factor, using "the first half-year of data from FY 2003 and comparing this data to the first half year of data for FY 2004." 69 Fed. Reg. at 49,277. This reduced the inflation factor from 26.8% in the 2005 Proposed Rule (69 Fed. Reg. at 28,376) to 18.76% in the 2005 Final Rule (69 Fed. Reg. at 49,277), and the threshold went from $35,085 in the 2005 Proposed Rule to $25,800 in the 2005 Final Rule. The Secretary followed the same approach in 2006 to arrive at an inflation factor of 14.94%. 70 Fed. Reg. at 47,494. However, the benefit of the more reasonable inflation factor could not fully overcome the distortion the Secretary perpetuated by continuing to use turbo-charging hospital data. Thus, while the steps that the Secretary took in 2005 and 2006

materially reduced the inflation factor (from 26.8% in 2004, to 18.76%, in 2005, to 14.94% in 2006), it reduced, but did not eliminate, the outlier underpayment ($1.4 billion in 2004, $1.1 billion in 2005, and $0.65 billion in 2006).

3. In the 2006 Final Rule, the Secretary stated that there were "special circumstances" that "made it especially difficult to project the increase in Medicare charges when calculating the outlier threshold" for 2004 and 2005. 70 Fed. Reg. at 47,494. For 2004, the Secretary stated that "the projected rate of charge inflation used to set the outlier threshold in the IPPS rule for FY 2004 [which was based on the charge inflation rate for 2000-2002] was substantially in excess of the actual rate of charge inflation during FY 2004," because "[w]e believe that hospitals changed their charging practices" as a result of the Outlier Correction Final Rule. *Id*. The Secretary stated that projecting charge inflation for 2005 also was difficult because "all" the data that the Secretary used to do so "reflected charges from discharges that occurred before the effective date" of the Outlier Correction Final Rule. *Id*. at 47,494-95.

The Secretary concluded that "the charge inflation used for setting both the FY 2004 and FY 2005 cost thresholds was atypical because of the significant growth in hospital charges in the years preceding the change to out outlier policy as well as the instability in hospital charging practices that followed the adoption of our new outlier policy." *Id*. at 47,495. This is a red herring because, as vividly explained in the IFR, the explosive growth in hospital charges was not due to any industry-wide practice.

Rather, it was mostly the result of the "dramatic increase in charges" by the 123 turbo-chargers. IFR at 18 (JAXXX). By failing to remove the turbo-chargers' data from her projections, the Secretary perpetuated the distorted legacy of the turbo-chargers.

2. *The Secretary Acted Arbitrarily and Capriciously when Setting the 2004-2006 Outlier Thresholds by Refusing to Exclude CCR Data from Turbo-Charging Hospitals or Otherwise Address the Distortion Caused by Using Historical CCRs.*

The Secretary also acted arbitrarily and capriciously by calculating the 2004-2006 outlier thresholds using improperly high CCRs (from the turbo-charging era) that failed to account for what the Secretary had repeatedly acknowledged were declining CCRs and increased charges, mostly caused by turbo-charging hospitals. This problem arose because the Secretary calculated the 2004-2006 thresholds using the "charge methodology."

At the beginning of the DRG system in 1983, the Secretary used the "charge methodology." From 1994 through 2002, the Secretary used a "cost methodology" to address "a continued trend" of declining CCRs.

> Over time, charges have continued to increase at a faster rate than costs, so that cost-to-charge ratios have been declining . . . As a result, actual payments may be lower than estimated. In order to alleviate this problem, we are using a cost inflation factor rather than a charge inflation factor to estimate FY 1994 costs.

58 Fed. Reg. 46,270, 46,347 (Sept. 1, 1993). The "cost methodology" projected the outlier threshold using an inflation factor unaffected by changes in CCRs.

The "charge methodology" projected the outlier thresholds at issue using historical CCRs and charge inflation factors that were too high because of turbo-charging hospital data. The "charge methodology" is reasonable during a period of turbo-charging only if concurrent, real-time CCRs are used to reduce the excessively inflated projected charges to projected costs. That did not occur in 2004-2006 because the Secretary used historical CCRs that overestimated outlier payments, resulting in thresholds that were too high.

In the IFR, the Secretary addressed the concern that historical CCRs that were too high would not properly reduce charges by eliminating both the inflation factor and the CCRs from turbo-charging hospitals when recalculating the threshold in light of the elimination of turbo-charging. IFR at 36 (JAXXX). If the Secretary had used the "cost methodology" from 2004-2006, she would have calculated the thresholds using costs for the upcoming year that were projected based on an inflation factor that was determined using changes in hospitals' costs, not charges, and therefore was untainted by turbo-charged data. The Secretary, however, used the "charge methodology" for 2004-2006, making no effort to mitigate the distortions caused by using a charge inflation factor that included turbo-charging hospital data and by using historical CCRs that were too high and not even acknowledging the *possibility* of excluding the distorted data from turbo-charging hospitals.

So, using the "charge methodology" in 2004, the Secretary applied actual CCRs from 2000 ("for most hospitals, the latest available cost data are from FY 2000," 68 Fed. Reg. at 45,476) to turbo-charged 2002 charge data, and then projected it forward using a charge inflation factor also tainted by turbo-charged data. This was unreasonable because the use of CCRs from 2000 did not adequately reduce charges from turbo-charged 2002 data that had been inflated to 2004 using a turbo-charged inflation factor to projected costs for 2004, so that projected costs would be anything close to actual.

3. *The Secretary Acted Arbitrarily and Capriciously when Setting the 2004-2006 Outlier Thresholds by Failing to Address the IFR.*

The Secretary also acted arbitrarily and capriciously by failing to disclose that she had studied the problem caused by including the distorted charge inflation and CCR data from turbo-charging hospitals and previously come to the conclusion that it was "necessary" to exclude the turbocharging hospitals' corrupted charge and CCR data in order to calculate an outlier threshold that satisfied the statute and 5.1% target. IFR at 34 (JAXXX).

The CMS Administrator testified before Congress that the approach presented in the IFR was not effectuated because OMB would not agree to it. Scully Testimony at 13 (JAXXX). The problem for the Secretary here is that the data in the IFR precisely supported the approach presented in it and not necessarily the approach ultimately taken in the Outlier Correction Proposed and Final Rules. The Secretary

responded by pretending the IFR never existed. She ignored the data and the considered approach laid out therein; data and an approach she wanted to see as an interim final rule. And the Secretary would have succeeded at burying the truth if not for the fortuitous uncovering of the IFR while this case was pending in the district court. This Court has never condoned an agency failing to disclose a solution to a regulatory problem that the agency itself believed was "necessary," only to be overruled by an agency (OMB) that Congress did not entrust with the administration of the statute in question.

This conduct by the Secretary is particularly problematic here, because from the IFR the Secretary was well aware that unless she lowered the outlier threshold sufficiently, the redistribution in outlier payments she sought to achieve in the IFR, $420 million from the few turbocharging hospitals to the almost 3800 non-turbocharging hospitals, would not occur. Indeed, the threshold in the final rule for 2004 was not dramatically different from the threshold she was attempting to correct in 2003. IFR at 52-53(JAXXX-XX). Instead, without even discussing this problem, the Secretary ignored the needs of these hospitals.

At a minimum, the agency entrusted by Congress should be required to disclose during the rulemaking process all significant potential solutions the agency has developed, in order to demonstrate that the agency has not "entirely failed to consider an important aspect of the problem [or] offered an explanation for its decision that

runs counter to the evidence before the agency . . . ." *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 63 (1983). The failure to do so constitutes agency action that is arbitrary and capricious.

There is no merit to the district court's conclusion that the Secretary had no duty to explain why she did not follow the IFR because "the IFR's exclusion of data from 123 turbo-charging hospitals never represented agency policy." Slip Op. at 11 (JAXXX). Because this Court has found Medicare policy established by sub-regulatory issuances without Secretarial signature (*Sentara-Hampton Gen. Hosp. v. Sullivan*, 98 F.2d 749, 759-60 (D.C. Cir. 1992)), the IFR (signed by the Secretary) surely represents agency policy. Moreover, *PLMRS Narrowband Corp. v. F.C.C.*, 182 F.3d 995 (D.C. Cir. 1999), cited by the district court, is inapt because it involved adjudication, not rulemaking. The district also cited (with a weak *cf.* modifier), *Kennecott Utah Copper Corp. v. U.S. Dep't of Interior*, 88 F.3d 1191 (D.C. Cir. 1996), which also is inapt because it addresses the right of the public to comment on a draft rule, not the agency's failure to address significant potential solutions the agency actually developed.

4. *The 2004-2006 Outlier Thresholds Must Be Set Aside and this Action Remanded to Calculate the Underpayment.*

The outlier thresholds in the 2004-2006 Rulemakings were arbitrary and capricious for six reasons. First, by pretending the IFR did not exist and, therefore, not addressing the option of excluding the turbo-charging hospital data, the Secretary

failed to "consider reasonably obvious alternative rules and explain its reasons for rejecting alternatives in sufficient detail to permit judicial review." *See, e.g., Walter O. Boswell Mem'l Hosp. v. Heckler*, 749 F.2d 788, 797 (D.C. Cir. 1984) (internal citations and quotations omitted); *Chamber of Commerce v. SEC*, 412 F.3d 133 (D.C. Cir. 2005). The district court held that the exclusion of turbo-charging hospital data was not an "alternative so 'obvious' that the Secretary need address it, unprompted by commenters, in a subsequent rulemaking." January 6, 2014 Mem. Op. at 12 (JAXXX). This holding lacks merit because the discussion of the exclusion of turbo-charging hospital data in the IFR combined with the comment specifically requesting that the Secretary "factor in the calculation of the threshold the fact that certain hospitals have distorted their charges significantly (68 Fed. Reg. at 45,477), shows that this was, in fact, an alternative that the Secretary was required to address. The Secretary also acted arbitrarily and capriciously by not adequately responding to relevant and significant comments. *Cape Cod Hosp. v. Sebelius*, 630 F.3d 203, 211-12 (D.C. Cir. 2011).

Second, the Secretary's 2004-2006 outlier thresholds were counter to the data and methodologies before her. *See, e.g., Advocates for Highway & Auto Safety v. FMCSA*, 429 F.3d 1136, 1139-40 (D.C. Cir. 2005). The Secretary acknowledged the distorting effect of turbo-charging hospital data, charge inflation in the years used to determine these thresholds, and declining CCRs, but made no effort to address them in

2004 and addressed only partially the inflation factor in 2005 and 2006, ignoring the distorting effect of turbo-charging hospital data and declining CCRs.

Third, the Secretary relied on data that she knew had poor predictive value when better alternatives were available. *See, e.g.*, *County of LA*, 192 F.3d at 1021.

Fourth, the Secretary's projections were not rationally related to the facts found and it irrationally maintained its model in the face of its repeated failures (outlier underpayments in 2004, 2005, and 2006). *Am. Petroleum Inst. v. EPA*, 706 F.3d 474, 477 (D.C. Cir. 2013); *see also, Appalachian Power Co. v. EPA*, 249 F.3d 1032, 1053 (D.C. Cir. 2001) ("[M]odel assumptions must have a 'rational relationship' to the real world.") (Citations omitted). The district court erred by finding that "it is irrelevant that the fixed loss thresholds established for FFYs 2004-2006 actually resulted in underpayments" because the "relevant question is only whether the predictive methodologies used to set those thresholds were arbitrary and capricious as judged by the record before the Secretary at the time each threshold was set." January 6, 2014 Mem. Op. at 8, n.8 (JAXXX). The underpayments here are relevant because they corroborate the precise results that the IFR anticipated. IFR at 34 (JAXXX).

The district court also erred by finding (Mem. Op. at 6 (JAXXX)) that its review is "particularly deferential" because the "agency's decision is 'primarily predictive,'" citing *Rural Cellular Ass'n v. FCC*, 588 F.3d 1095, 1105 (D.C. Cir. 2009). However, this level of deference applies only if the Secretary meets her burden

of "acknowledg[ing] factual uncertainties and identify[ing] the considerations [she] found persuasive" (*id.*), which did not happen here. *See also In re Core Commc'ns, Inc.*, 455 F.3d 267, 282 (D.C. Cir. 2006).

Fifth, the Secretary treated similar situations differently without adequate explanation. *See, e.g.*, *County of LA*, 192 F.3d at 1022-23. Here, the Secretary treated the data from turbo-charging hospitals under the virtually identical situations presented in the IFR and the 2004-2006 Rulemakings.

Sixth, the Secretary failed to provide an explanation for her decision, including a rational connection between the facts found and the choice it made. *See, e.g.*, *State Farm*, 463 U.S. at 43. The Secretary has never explained why it was rational to include unmitigated turbo-charging data and obsolete CCRs when calculating the thresholds at issue. The Secretary also did not explain how she took into account the reduced payments to turbo-charging hospitals, which she addressed in the IFR by setting the threshold low enough to redistribute the reduced payments to non-turbo-charging hospital in order to meet the 5.1% outlier payment target. Thus, the outlier thresholds for 2004-2006 must be set aside and this action remanded for purposes of calculating the underpayment resulting from the Secretary's improper actions.

B. The Secretary's Failure to Use "Best Available Data" to Calculate the 2004-2006 Outlier Thresholds was Improper Under the APA.

The Secretary also acted arbitrarily and capriciously by not using the best available charge data when establishing the thresholds at issue. The Secretary used

charge data that she knew was overstated, leading to outlier thresholds that she knew were unreasonably high. The Secretary, however, could have used better data. This is most pronounced in 2004, where the Secretary used inflation data that conflicted with what the Secretary set forth in the IFR (February 2003) and the 2005 Final Rule (August 1, 2004), with no explanation or justification for choosing the 2004 option.

This violates the "best available data" standard, which the Secretary imposed on herself when making outlier calculations: "Each year we set the outlier thresholds for the upcoming fiscal year by making projections based on the best available data" (65 Fed. Reg. 47,054, 47,114 (Aug. 1, 2001)). Here, the best available data required the exclusion of the data from turbo-charging hospitals. The failure to use best available data also violates the APA. *Gas Appliance Mfrs. Ass'n v. DOE*, 998 F.2d 1041, 1047 (D.C. Cir. 1993).

C. The District Court Erred by Refusing to Order the Secretary to Present Complete Rulemaking Records.

As discussed above, the Secretary unlawfully refused to disclose or address the options presented in the IFR. The Secretary also purposefully avoided a comment,[21] the truthful response to which would have shown that the Secretary had, in fact,

[21] "One commenter requested that CMS factor in the calculation of the threshold the fact that certain hospitals have distorted their charges significantly." 68 Fed. Reg. at 45,477.

considered excluding turbo-charging hospital data.[22] Sophisticated commenters, such as the Federation of American Hospitals, rely on the Secretary being forthcoming with data that is necessary for the modeling that these commenters undertake to determine the validity of the threshold.

In the 2004-2006 Rulemakings, the Secretary refused to disclose important materials which, if revealed, would have given the Hospitals more insight into how the thresholds for those years were determined. The Hospitals moved to compel production of various categories of materials that were indisputably before the agency during the Rulemakings.

Data used to "approximate" the CCRs in 2004. The Hospitals moved to compel production of the actual CCRs that the Secretary used to calculate the 2004 threshold. If the Hospitals had a better understanding of the CCRs that the Secretary used for purposes of calculating the 2004 threshold, including the "attempt" to calculate special CCRs for the 50 hospitals that the Secretary believed would be subject to reconciliation, they could have better assessed the distorting effect of including data from the turbo-charging hospitals.

[22] The district court barred the Hospitals from challenging the 2005 and 2006 charge inflation factors on the grounds that the Secretary did not exclude the turbo-charging hospital data because there was no specific comment on that point, although, at the least, the Federation of American Hospitals commented on charge inflation during the 2005 and 2006 Rulemakings. AR(2005)1979.16-17; (2006)1400 (JAXXX-XXX). This holding has no factual or legal merit and unseemly rewards the agency for refusing to discuss an option in the IFR.

However, the Secretary's deponent refused to identify the CCR data the Secretary used to determine the 2004 threshold (Hefter Dep. Tr. [Dkt 84-1] 112.1-22 (JAXXX)) and the Court refused to order the Secretary to add this data to the 2004 rulemaking record. The data that the Secretary used to calculate the 2004 CCRs is essential because the Secretary did not get CCR data from Hospitals' tentatively settled cost reports (claimed to be the most accurate source), but got it from another undisclosed source.

"Trimmed" versions of the MedPAR files. The Secretary failed to include in the rulemaking record the "trimmed" data subsets that the Secretary's deponent confirmed were used by the Secretary to calculate the thresholds at issue. *See, e.g.*, Hefter Dep. Tr. [Dkt 84-1] 61.7-62.8 and 126.16-127.6 (JAXXX-XXX). While the Secretary provided the complete data sets, the Secretary did not use these particular sets to calculate the thresholds. Rather, the Secretary "trimmed" these data files for purposes of establishing the thresholds. The district court, however, refused to order the Secretary to include in the rulemaking records the data actually used.

The IFR. The district court improperly refused to include the IFR in the rulemaking records for 2005 and 2006, even though the Secretary's failure to address the option of excluding turbo-charging hospital data, and the other issues in the IFR, also caused the outlier threshold to be unreasonably high for those years.

CMS Administrator Scully's Testimony. The district court refused to include the Scully Testimony in the Rulemaking record for any of the years at issue, stating that the Hospitals had failed "to provide concrete evidence that the Scully testimony was considered by the Secretary during the challenged rulemakings" [Dkt 113 at 23] despite the fact that this testimony was given while the agency he was overseeing was in the process of writing the 2004 Proposed Rule and the Outlier Correction Final Rule. The district court discounted Mr. Scully's testimony as "his personal opinions" despite a declaration from Mr. Scully explaining: "As the CMS Administrator, I was called upon on numerous occasions to testify before Congress as the head of that agency. In every instance, including my testimony before the U.S. Senate on March 11, 2003, my testimony represented the official position of CMS and did not represent any of my personal views." Exhibit to Plaintiffs' Supplemental Memorandum ("Pls.' Supp. Mem") [Dkt 119-1] (JAXXX).

All of this is unacceptable because the reviewing court must "have before it neither more nor less information than did the agency when it made its decision." *Boswell Mem'l*, 749 F.2d at 792.[23]

[23] Even if the Scully Testimony is not included in the Rulemaking records, it is relevant, public information and the Court should take judicial notice of it to learn more about the background of the issues in this action. *United States v. Penn Foundry & Mfg. Co.*, 337 U.S. 198, 216 (1949) (Douglas, J. concurring).

D. The Rulemakings Must be Set Aside Because the Secretary Failed to Consider the IFR.

The Secretary argued below that the IFR "was not prepared or considered in connection with any of the three rulemakings in dispute in this case." Secretary's Summary Judgment Reply Brief [Dkt 100] at 7 (emphasis added)). The failure of an agency to consider "important factors" during the rulemaking process requires the rulemaking to be set aside as "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. §706(2)(A); *State Farm*, 463 U.S. at 43. An agency "must consider reasonably obvious alternative rules and explain its reasons for rejecting alternatives in sufficient detail to permit judicial review." *Boswell Mem'l*, 749 F.2d at 797 (internal citations and quotation marks omitted). This Court has stated that the "failure of an agency to consider obvious alternatives has led uniformly to reversal." *Yakima Valley Cablevision, Inc. v. FCC*, 794 F.2d 737 n.36 (D.C. Cir. 1986). The IFR contains "important factors" and/or "obvious alternatives" that the Secretary should have considered, but concededly did not. The extreme relevance of these factors cannot be over-emphasized, given that they were endorsed as a final rule by the Secretary.

IX. CONCLUSION

For the foregoing reasons, this Court should hold that the Secretary's 2004-2006 outlier thresholds are contrary to law and arbitrary and capricious and remand for the Secretary to calculate the underpayments for those years.

Dated: July 31, 2014

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

I HEREBY CERTIFY pursuant to Federal Rule of Appellate Procedure 32(a)(7)(C) that the foregoing Brief complies with the type-volume limitation of 14,000 words set forth in Rule 32(a)(7)(B), in that it contains 13,978 words in content.

Dated: July 31, 2014

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CERTIFICATE OF SERVICE

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